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EXAMINER

NGUYEN, QUANG

ART UNIT PAPER NUMBER

1636

DATE MAILED: 02/10/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/720,549

Applicant(s)

TOFANI, SANTI

Examiner

Quang Nguyen, Ph.D.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-76 is/are pending in the application.
- 4a) Of the above claim(s) 21-60, 69, 71, 73 and 75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-68, 70, 72, 74 and 76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This application has been transferred to examiner Quang Nguyen, Ph.D. in GAU 1636.

Claims 21-76 are pending in the present application.

Applicant's election with traverse of Group II (claims 61-68, 70, 72, 74 and 76) in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the claims of Group II drawn to a method of using SELF non-thermal fields for biotechnological gene modification utilize the means of selectively interfering with pathological cell survival processes that are claimed with the means claims of Group I, and that the combination of a means or product and method of using that means or product are combined to achieve unity of invention. This is not found persuasive because the method of using SELF non-thermal fields for biotechnological genes modifications of Group II is a different method having different starting materials, different method steps, different desired outcomes (e.g., potential uses of modified biotechnological genes in gene therapy) and different technical considerations for achieving the desired outcomes from the method of using SELF non-thermal fields for selectively interfering with pathological cells' survival (the first method being recited) of Group I. For example, the method of Group II does not even require the use of any cell (note that the claims are directed to biological genes modifications), let alone interfering with pathological cells' survival as required by the method of Group I. Therefore, the inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under

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PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons set forth above.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 21-60, 69, 71, 73 and 75 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Claims 61-68, 70, 72, 74 and 76 are examined on the merits herein.

Claim Objections

Claim 61 is objected to because the term "SELF" should be spelled out in full at the first occurrence of the term. Appropriate correction is required.

Specification

The abstract is objected because it contains the legal phraseology "means".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 61-68, 70, 72, 74 and 76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains

subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in the determination of an enabling disclosure have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex parte Forman*, (230 USPQ 546 (Bd Pat. Appl & Unt, 1986); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)).

The claims are directed to a method of using SELF [static magnetic (S) and extremely low frequency (ELF)] non-thermal fields for biotechnological genes. modifications, comprising applying said SELF non-thermal fields to said biotechnological genes to be modified, wherein said SELF non-thermal fields have intensity in the range between 1 and 100 mT.

The specification teaches by exemplification showing that by applying SELF magnetic fields, apoptosis is induced in cultured human colon adenocarcinoma WiDr cells and human breast cancer MCF-7 cells, but not in normal human lung MRC-5 fibroblasts, with significant apoptosis effect was observed at the field intensity of 2 mT. However, the induced apoptosis does not depend upon SELF field frequency. Applicant further demonstrates that SELF fields have an inhibitory tumor growth effect in an experimental model of nude mice inoculated subcutaneously with human colon adenocarcinoma WiDr cells, as well as a decreased in p53 gene expression in exposed

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mice tumors. The above evidence has been noted and considered. However, the instant specification is not enabled for the presently claimed invention for the following reasons.

(1) *The breadth of the claims.* The claims are directed to a method of using SELF non-thermal fields for modifying any biotechnological genes, wherein said SELF non-thermal fields have intensity in the range between 1 and 100 mT.

(2) *The state and the unpredictability of the prior art.* At the effective filing date of the present application (6/24/1998), nothing was known in the prior art on how to use methods of SELF non-thermal fields for biotechnological gene modification, let alone the modification of a mutant p53 gene by SELF non-thermal fields having intensity in the range between 1 and 100 mT (see claim 68), as evidenced by the teachings of Canedo et al. (U.S. Patent No. 5,752,911) and Blackman et al. (U.S. Patent No. 5,919,679). Additionally, Blackman et al. stated "The results of a number of studies suggest that low intensity and low-frequency electric and magnetic fields may influence physiological processes in biological systems. However, most theoretical models developed to date have been unable to establish a predictive association between low-intensity field exposure and biological results" (col. 2, lines 14-19), and "A variety of theoretical models have been developed to describe the interaction of different combinations of static (DC) and extremely-low-frequency time-varying (AC) magnetic fields with living systems.....Most of the above-described models are largely descriptive, without being predictive" (col. 2, lines 45-55)

(3) The amount of direction or guidance provided. Apart from the exemplification showing that SELF fields have an inhibitory tumor growth effect in an experimental model of nude mice inoculated subcutaneously with human colon adenocarcinoma WiDr cells, as well as a decrease in p53 gene expression in exposed mice tumors, the instant specification fails to provide sufficient guidance for a skilled artisan on **how to use methods of SELF non-thermal fields for any biotechnological gene modification**, including modifying any mutant p53 gene (see claim 68). It should be noted that enablement requires the specification to teach how to make and/or use the claimed invention. Since the prior art at the effective filing date of the present application does not provide any guidance on this matter, it is incumbent upon the present application to do so. Moreover, the interaction of different combinations of static and extremely low frequency time varying magnetic fields with living systems in various theoretical models has been noted by Blackman et al. (U.S. Patent No. 5,919,679) are largely descriptive, without being predictive, then how could one use SELF non-thermal fields to modify any biotechnological gene with any degree of predictability to attain any beneficial or desirable effects or results (**how to use**)? Given the lack of sufficient guidance provided by the instant specification, it would have required undue experimentation for a skilled artisan on how to make and use the method as claimed.

(4) Working examples. There is an absence of an example showing how to use methods of SELF non-thermal fields for biotechnological gene modification, wherein the SELF non-thermal fields have intensity in the range between 1 and 100 mT.

Accordingly, due to the lack of sufficient guidance provided by the specification regarding to the issues set forth above, the unpredictability and the state of the art on the make and use SELF non-thermal fields for any biotechnological gene modification, and the breadth of the claims, it would have required undue experimentation for one skilled in the art to make and use the presently claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 61-67, 70, 72, 74 and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 61, it is unclear what is encompassed by the term "biotechnological genes". Which genes would or would not be considered as "biotechnological genes"? Since the term is not defined in the present specification, the metes and bounds of the claims are not clearly determined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 61, 63 and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Canedo et al. (U.S. Patent No. 5,752,911).

Canedo et al. teach a method of subjecting a patient with a history of epileptic seizures to the action of magnetic fields applied externally. The applied magnetic fields which have time-varying magnetic field components generated at low frequencies of less than about 300 Hz (qualified as an ELF, see specification page 1, lines 26-32) as well as static magnetic field components with an intensity of from about 40 to about 80 mT (see Summary of the Invention). Since the patient contain tissues comprising cells having genes, and due to the vagueness of a biotechnological gene, the method taught by Canedo et al. contains the same step and the same limitation as the presently claimed invention.

Accordingly, Canedo et al. anticipate the instant claims.

Conclusions


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636.

Quang Nguyen, Ph.D.


JAMES KETTER
PRIMARY EXAMINER